

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESale PRICE  
LITIGATION

THIS DOCUMENT RELATES TO:  
*State of Iowa v. Abbott Laboratories, et al.*

MDL No. 1456  
Master File No.: 01-CV-12257-PBS  
(original S. D. Iowa No. 4:07-cv-00461-  
JAJ-CFB)

Judge Patti B. Saris

**ANSWER AND AFFIRMATIVE DEFENSES OF BAYER CORPORATION  
AND BAYER HEALTHCARE PHARMACEUTICALS INC.  
TO THE STATE OF IOWA'S COMPLAINT**

Defendants Bayer Corporation ("Bayer Corp.") and Bayer HealthCare Pharmaceuticals Inc. ("BHCP," and collectively with Bayer Corp., "Bayer"),<sup>1</sup> by and through their attorneys, hereby state as an Answer and Affirmative Defenses to the State of Iowa's Complaint, dated October 9, 2007, as follows:

**PRELIMINARY STATEMENT**

The State of Iowa's Complaint (the "Complaint") improperly refers to Bayer Corp., BHCP, other Defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against Bayer. This is insufficient to apprise Bayer of the allegations asserted against it. Bayer has nevertheless attempted to respond to Plaintiff's allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, Bayer is generally without knowledge or information

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<sup>1</sup> Unless otherwise specified, admissions and denials by "Bayer" below are made by both Bayer Corp. and BHCP.

sufficient to form a belief as to the truth of those allegations. Bayer states that it is answering Plaintiff's allegations solely on behalf of itself, even when Plaintiff's allegations refer to alleged conduct by Bayer and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, Bayer's failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or Bayer's reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

Bayer denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, Bayer specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Bayer has included in this Answer and Affirmative Defenses certain captions used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, those captions.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

**SPECIFIC RESPONSES**

1. Bayer admits that the State of Iowa (the “State”) seeks to bring this action as alleged in Paragraph 1 of the Complaint, but Bayer denies that there is any basis for the State to do so and denies that the State is entitled to any relief.

2. To the extent the allegations in Paragraph 2 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 2 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

3-4. To the extent the allegations in Paragraphs 3-4 are directed at Bayer, Bayer denies them. Bayer further denies the characterization of “spread” in Paragraphs 3-4. To the extent the allegations in Paragraphs 3-4 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

5. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

6. To the extent the allegations in Paragraph 6 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 6 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

7-8. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 7-8.

9. To the extent the allegations in Paragraph 9 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 9 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

10. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, except that it admits that it pays Medicaid rebates to Iowa and that such rebates lower the price Iowa Medicaid pays for Bayer's prescription drugs. To the extent the allegations in Paragraph 10 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

11. To the extent the allegations in Paragraph 11 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 11 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

12. To the extent the allegations in Paragraph 12 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 12 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

13. To the extent the allegations in Paragraph 13 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 13 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

14-15. Bayer admits that it voluntarily participates in the Iowa Medicaid program, but denies that it has violated any State or Federal law. To the extent the allegations in Paragraphs 14-15 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 14-15 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

16. To the extent the allegations in Paragraph 16 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 16 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

17. To the extent the allegations in Paragraph 17 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 17 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

18. Bayer admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiff with respect to any such NDCs. To the extent the allegations in Paragraph 18 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

19. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19. To the extent the allegations in Paragraph 19

refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

20. To the extent that the allegations in Paragraph 20 are directed at Bayer, Bayer denies them, except Bayer admits that it manufactures and sells prescription drugs and that it participates in the Iowa Medicaid Program. To the extent the allegations in Paragraph 20 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

21. Bayer admits that it conducts business in the State of Iowa.

22-27. The allegations in Paragraphs 22-27 are directed to other Defendants and require no response from Bayer. To the extent a response is deemed to be required, Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 22-27.

28. With respect to the allegations in Paragraphs 28 (a)-(b), Bayer Corp. admits that it is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania. Bayer Corp. admits that it is a wholly-owned United States subsidiary of Bayer AG. Bayer Corp. denies that it is involved in manufacturing and selling pharmaceuticals. BHCP admits that it is a wholly owned subsidiary of Bayer Corp. and the successor in interest to Bayer Pharmaceuticals Corporation, which no longer exists. BHCP admits that it is a Delaware corporation with its principal place of business at 6 West Belt, Wayne, New Jersey, and that it is involved in manufacturing and selling pharmaceuticals. Bayer otherwise denies the allegations in Paragraph 52.

28-58. The allegations in Paragraphs 28-58 are directed to other Defendants and require no response from Bayer. To the extent a response is deemed to be required, Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 28-58.

59. Bayer admits that the State seeks to bring this action as alleged in Paragraph 59, but Bayer denies there is any basis for the State to do so and denies that the State is entitled to any relief.

60-61. Paragraphs 60-61 state legal conclusions as to which no response is required. To the extent a response is deemed to be required, Bayer denies the allegations in Paragraphs 60-61, and notes that this captioned matter has been transferred to this Court by the Judicial Panel on Multi District Litigation, pursuant to 28 U.S.C. § 1407.

62. With respect to the allegations in Paragraph 62, Bayer admits that Medicaid was established by Title XIX of the Social Security Act. Bayer further states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

63. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63, except Bayer admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 63 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

64-65. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 64-65. To the extent the allegations in Paragraphs 64-65 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

66. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66, except admits that national drug codes are assigned to prescription drugs.

67. To the extent the allegations in Paragraph 67 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Bayer otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67.

68. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68. To the extent the allegations in Paragraph 68 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

69. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69. To the extent the allegations in Paragraph 69 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

70. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70.

71-72. To the extent the allegations in Paragraphs 71-72 are directed at Bayer, Bayer denies them. Bayer further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 71-72 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

73-80. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 73-80 or their subsections. To the extent the allegations in Paragraphs 73-80 or their subsections refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

81. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81, except that it admits that pricing compendia such as First DataBank and Medi-Span publish AWP's and FULs, and denies that Bayer has any control over such prices.

82. To the extent the allegations in Paragraph 82 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 82 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

83. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83.

84. To the extent the allegations in Paragraph 84 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 84 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

85. To the extent the allegations in Paragraph 85 are directed at Bayer, Bayer denies them, except that Bayer admits that Exhibit A purports to identify total expenditures by Defendant. To the extent the allegations in Paragraph 85 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

86. To the extent the allegations in Paragraph 86 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 86 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

87-89. To the extent the allegations in Paragraphs 87-89 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 87-89 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

90-92. To the extent the allegations in Paragraphs 90-92 are directed at Bayer, Bayer denies them. Bayer further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 90-92 are

directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

93-98. To the extent the allegations in Paragraphs 93-98 are directed at Bayer, Bayer denies them, except Bayer admits that it has provided the list price of its drugs to certain industry pricing compendia. Bayer further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 93-98 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

99. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99.

100. To the extent the allegations in Paragraph 100 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 100 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

101. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

102-108. The allegations in Paragraphs 102-108 require no response from Bayer on the grounds that Exhibit B does not name any Bayer drugs subject to the FUL. To the extent the allegations in Paragraphs 102-108 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

109. The allegations in Paragraph 109 require no response from Bayer on the grounds that the Iowa SMAC claims have been dismissed by the Court.

110-128. To the extent the allegations in Paragraphs 110-128 are directed at Bayer, Bayer denies them, except Bayer admits that it has executed a rebate agreement with HHS. Bayer further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Bayer. In any event, the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 110-128 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 110-128 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

129. To the extent allegations in this paragraph are directed to Bayer, Bayer admits only that in April 2003, Bayer Corp. pled guilty to a one-count Information alleging that Bayer Corp. failed to list particular drugs with the Food and Drug Administration in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*; that Bayer entered into a settlement covering these claims with federal and state governments, including Iowa; and that Iowa and other government agencies released all claims against Bayer related to the drugs that were the subject of the suit. Bayer denies

that Plaintiffs have accurately characterized the contents, findings, opinions, statements or conclusions of the matters leading to this settlement. To the extent the remaining allegations in Paragraph 129 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 129 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 129 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

130-132. To the extent the allegations in Paragraphs 129-132 are directed at Bayer, Bayer denies them, and further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Bayer. To the extent the allegations in Paragraphs 129-132 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 129-132 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

133. To the extent the allegations in Paragraph 133 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 133 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

134. To the extent the allegations in Paragraph 134 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 134 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 134 refer to the transcript of a

congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

135. To the extent the allegations in Paragraph 135 are directed at Bayer, they are denied. To the extent the allegations in Paragraph 135 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

136. To the extent the allegations in Paragraph 136 are directed at Bayer, they are denied, except Bayer admits that certain of its contracts are subject to confidentiality agreements and that Bayer does offer discounts to certain of its customers. To the extent the allegations in Paragraph 136 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

137. To the extent the allegations in Paragraph 137 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 137 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

138-139. To the extent the allegations in Paragraphs 138-139 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 138-139 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 138-139 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

140-141. To the extent the allegations in Paragraphs 140-141 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 140-141 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

142. To the extent the allegations in Paragraph 142 are directed at Bayer, Baxter denies them. To the extent the allegations in Paragraph 142 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

143. To the extent the allegations in Paragraph 143 are directed at Bayer, Bayer denies them. Bayer further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraph 143 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

144-145. To the extent the allegations in Paragraphs 144-145 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 144-145 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

146. To the extent the allegations in Paragraph 146 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 146 are directed at parties other

than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

147. To the extent the allegations in Paragraph 147 are directed at Bayer, Bayer denies them. Bayer further denies the characterization of “spread” in Paragraph 147. To the extent the allegations in Paragraph 147 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

148. To the extent the allegations in Paragraph 148 are directed at Bayer, Bayer denies them. Bayer further denies the characterization of “spread” in Paragraph 148. To the extent the allegations in Paragraph 148 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

149-150. To the extent the allegations in Paragraphs 149-150 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 149-150 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

151-152. To the extent the allegations in Paragraphs 151-152 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 151-152 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 151-152 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

153-154. To the extent the allegations in Paragraphs 153-154 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 153-154 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

155-157. To the extent the allegations in Paragraphs 155-157 are directed at Bayer, Bayer denies them. Bayer further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 155-157 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 155-157 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

158. To the extent the allegations in Paragraph 158 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 158 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

159-165. Bayer denies knowledge or information to form a belief as to the truth of the allegations in Paragraphs 159-165, except Bayer admits that it participates in the Federal Medicaid Rebate Program through which Iowa Medicaid is obligated to reimburse providers for Bayer drugs. Bayer further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood,

including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraphs 159-165 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

166. To the extent the allegations in Paragraph 166 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 166 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

167-171. To the extent that the allegations in Paragraphs 167-171 are directed at Bayer, Bayer denies them, except Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegation that the “Iowa Medicaid Program spent over \$1.6 billion for defendants’ drugs between 1992 and 2005 alone.” To the extent the allegations in Paragraphs 167-171 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

172-177. With respect to the allegations in Paragraphs 172-177, Bayer admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 172-177 or Exhibit B are directed at Bayer, Bayer denies them. Bayer further denies the characterization of “spread” in Paragraphs 172-177 and Exhibit B. To the extent the allegations in Paragraphs 172-177 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

178. To the extent the allegations in Paragraph 178 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 178 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

179. To the extent the allegations in Paragraph 179 are directed at Bayer, Bayer denies them, except Bayer admits that its contracts with purchasers sometimes included discounts. To the extent the allegations in Paragraph 179 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

180. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 180 or the exhibit referenced therein are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

181-262. The allegations in Paragraphs 181-262 are directed to other Defendants and require no response from Bayer. To the extent a response is deemed to be required, Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 181-262.

263. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 263 or the exhibit referenced therein, except Bayer denies that it engaged in any “fraud.”

264. Bayer denies the allegations in Paragraph 264 and the exhibit referenced therein.

265-271. Bayer denies the allegations in Paragraphs 265-271. Bayer further states that the allegations in Paragraphs 265-271 are covered by Bayer's 2001 and 2003 settlement agreements with the federal and state governments, including the State of Iowa. Bayer denies that it engaged in any wrongful conduct with respect to AWP or Best Price, and denies the remaining allegations of Paragraphs 265-271.

272. Bayer Corp. admits that it has been named as a defendant in lawsuits filed by the states of Alabama, Hawaii, Illinois, Kentucky, Mississippi, Montana, Pennsylvania, and the City of New York and 46 New York Counties, and denies that it engaged in any "wrongdoing." BHCP admits that Bayer Pharmaceuticals Corporation has been named as a defendant in lawsuits filed by the states of Alabama and Mississippi, and denies that it engaged in any "wrongdoing."

273-274. Bayer denies that it engaged in any wrongful conduct with respect to AWP and Best Price, and respectfully refers to its SEC filings for a discussion of any known government investigations of its pricing practices. Bayer further states that it entered into a settlement agreement in 2001 with the federal and state governments, including the State of Iowa, for claims relating to Koate, Kogenate, Konyne-80, Gamimune N 5%, Gamimune N 10%, and Thrombate III, in which the governments released all claims against Bayer related to the subject drugs. Bayer denies any remaining allegations in Paragraphs 273-274.

275. Bayer admits that in 2001 it reached a settlement agreement with the federal and state governments, including the State of Iowa, for claims related to Koate, Kogenate, Konyne-80, Gamimune N 5%, Gamimune N 10%, and Thrombate III. By the 2001 settlement agreement, the governments, including the State of Iowa, released all claims related to the subject drugs in exchange for Bayer's payment of \$14 million. Bayer denies any remaining allegations in Paragraph 275.

276. Bayer denies that it engaged in any wrongdoing with respect to the reporting of drug prices. The qui tam action cited in Paragraph 276 speaks for itself, and Bayer denies that Plaintiff has accurately characterized the contents, findings, opinions, statements or conclusions of the qui tam action. Bayer admits that in 2001 it reached a settlement agreement with federal and state governments, including the State of Iowa, for claims related to Koate, Kogenate, Konyne-80, Gamimune N 5%, Gamimune N 10%, and Thrombate III. The DOJ's January 23, 2001, press release cited in Paragraph 276 speaks for itself, and Bayer denies that Plaintiff has accurately characterized the statements of the press release. Bayer denies any remaining allegations in Paragraph 276.

277-278. Bayer denies that it engaged in any wrongdoing with respect to AWP. Bayer states the 2001 settlement agreement and corporate integrity agreement cited in Paragraphs 277-278 speak for themselves, and Bayer denies that Plaintiff has accurately characterized the contents of the settlement agreement and corporate integrity agreement. Bayer admits that in 2001 it entered a settlement agreement and corporate integrity agreement with federal and state governments, including the State of Iowa. Bayer further admits that under the settlement agreement and corporate integrity agreement, it has provided federal and state governments, including the State of Iowa, with the quarterly

average sale prices for all Bayer drugs since summer 2001 and that the 2001 settlement agreement requires such reporting for a period of five years. Bayer denies the remaining allegations in Paragraphs 277-278.

279. Bayer denies that it engaged in any wrongdoing with respect to Medicaid reimbursements or drug pricing. Bayer admits that in 2003, it entered a civil settlement agreement with federal and state governments, including the State of Iowa, to resolve allegations that it misrepresented the “Best Price” for two of its products, Cipro and Adalat CC. Bayer further admits that pursuant to this civil settlement agreement, it paid approximately \$242 million. Bayer further admits that in 2003, Bayer Corp. entered a guilty plea to a one-count Information alleging that Bayer Corp. failed to properly list Cipro with the Food and Drug Administration in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., and that Bayer agreed to pay approximately \$5.6 million in connection with the plea. Bayer denies the remaining allegations in Paragraph 279.

280. Bayer denies the allegations in Paragraph 280. Bayer further states that it entered into these settlements to resolve the AWP and Best Price claims in this case. Additionally, Bayer has been providing federal and state governments, including the State of Iowa, with the quarterly average sale prices for all Bayer drugs pursuant to the 2001 settlement agreement, further precluding any claims based on the reporting of drug prices after summer 2001.

281-532. The allegations in Paragraphs 281-532 are directed to other Defendants and require no response from Bayer. To the extent a response is deemed to

be required to the remaining paragraphs, Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 281-613.

533. To the extent allegations in this paragraph are directed to Bayer, Bayer admits only that in April 2003, Bayer Corp. pled guilty to a one-count Information alleging that Bayer Corp. failed to list particular drugs with the Food and Drug Administration in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*; that Bayer entered into a settlement covering these claims with federal and state governments, including Iowa; and that Iowa and other government agencies released all claims against Bayer related to the drugs that were the subject of the suit. Bayer denies that Plaintiffs have accurately characterized the contents, findings, opinions, statements or conclusions of the matters leading to this settlement. To the extent the remaining allegations in Paragraph 533 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 533 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

534-613. The allegations in Paragraphs 534-613 are directed to other Defendants and require no response from Bayer. To the extent a response is required, Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 281-613.

614-616. To the extent the allegations in Paragraphs 614-616 are directed at Bayer, Bayer denies them, except Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegation that Iowa's Medicaid program "spent over \$1.6 billion for defendants' drugs in state and federal dollars from 1992 through 2005

alone.” To the extent the allegations in Paragraphs 614-616 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

617-632. To the extent the allegations in Paragraphs 617-632 are directed at Bayer, Bayer denies them. Bayer further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 617-632 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 630 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

## COUNT I

### **VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

633. In response to Paragraph 633, Bayer repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 632.

634-642. To the extent the allegations in Paragraphs 634-642 are directed at Bayer, Bayer states that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Bayer denies the allegations as to itself. To the extent the allegations in Paragraphs 634-642 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

**COUNT II**

**BREACH OF CONTRACT**

643. In response to Paragraph 643, Bayer repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 642.

644-651. To the extent the allegations in Paragraphs 644-651 are directed at Bayer, Bayer states that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, Bayer denies the allegations as to itself. To the extent the allegations in Paragraphs 644-651 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth.

**COUNT III**

**IOWA CONSUMER FRAUD ACT  
(Iowa Code § 714.16)**

652. In response to Paragraph 652, Bayer repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 651.

653. To the extent the allegations in Paragraph 653 and the exhibits referenced therein are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraph 653 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 653 refers to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

654-657. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto refer to statutes, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto contain legal conclusions, no response is required.

#### **COUNT IV**

#### **FRAUD**

658. In response to Paragraph 658, Bayer repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 657.

659-662. To the extent the allegations in Paragraphs 659-662 and the exhibits referenced therein are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 659-662 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 659-662 refer to Iowa law, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 659-662 contain legal conclusions, no response is required.

**COUNT VIII**  
**UNJUST ENRICHMENT**

663. In response to Paragraph 663, Bayer repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 662.

664-666. To the extent the allegations in Paragraphs 664-666 are directed at Bayer, Bayer denies them. To the extent the allegations in Paragraphs 664-666 are directed at parties other than Bayer, Bayer denies knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 664-666 contain legal conclusions, no response is required.

667-675. Bayer denies that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 667-675 of the Complaint.

**WHEREFORE**, Bayer demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

**AFFIRMATIVE DEFENSES**

Bayer reasserts and incorporates herein by reference the assertions of paragraphs 1 through 675 hereof.

**First Affirmative Defense**

Plaintiff fails to state a claim against Bayer upon which relief may be granted.

**Second Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because it did not rely on any alleged misrepresentations or fraud by Bayer. Plaintiff knew that providers could obtain Bayer drugs at prices below AWP prior to the relevant time period stated in the Complaint.

**Third Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

**Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

**Fifth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the state action doctrine.

**Sixth Affirmative Defense**

To the extent Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Bayer based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

**Seventh Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Bayer in judicial, legislative, or administrative proceedings of any kind or at any level of government.

**Eighth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiff's claims.

**Ninth Affirmative Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, and the Prescription Drug, Improvement and Modernization Act of 2003, including all amendments to the same and all regulations promulgated thereunder.

**Tenth Affirmative Defense**

Plaintiff's claims against Bayer are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

**Eleventh Affirmative Defense**

Plaintiff fails to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Bayer contained in the Complaint.

**Twelfth Affirmative Defense**

Any and all actions taken by Bayer with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Thirteenth Affirmative Defense**

Bayer's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

**Fourteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a consumer within the meaning of the Iowa Consumer Fraud Act.

**Fifteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a person within the meaning of the Iowa Consumer Fraud Act.

**Sixteenth Affirmative Defense**

Some or all of Plaintiff's claims against Baxter arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**Seventeenth Affirmative Defense**

Bayer denies that Plaintiff has a valid consumer protection claim against Bayer under the Iowa Consumer Fraud Act. However, if such claim is found to exist, Bayer pleads all available defenses under the Act.

**Eighteenth Affirmative Defense**

To the extent that Plaintiff attempts to seek equitable relief against Bayer, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

**Nineteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

**Twentieth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by Bayer after the filing of the Complaint.

**Twenty-First Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Twenty-Second Affirmative Defense**

Plaintiff's claims against Bayer are barred, in whole or in part, due to their failure to join indispensable parties.

**Twenty-Third Affirmative Defense**

Plaintiff's claims against Bayer are barred, in whole or in part, because Plaintiff has not suffered damages as a result of the matters alleged in the Complaint.

**Twenty-Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Bayer; (2) because Plaintiff would be unjustly enriched if allowed to recover any portion

of the damages alleged in the Complaint; and (3) because damages are speculative and remote and because of the impossibility of ascertaining and allocating alleged damages.

**Twenty-Fifth Affirmative Defense**

Bayer is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Twenty-Sixth Affirmative Defense**

Plaintiff's claims against Bayer are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Iowa Constitution.

**Twenty-Seventh Affirmative Defense**

Plaintiff's claims against Bayer are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

**Twenty-Eighth Affirmative Defense**

Plaintiff's claims against Bayer are barred, in whole or in part, because they violate Bayer's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Iowa Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Twenty-Ninth Affirmative Defense**

Plaintiff's claims against Bayer are barred because Plaintiff and/or its agents knew and were aware that AWP was not an actual average of wholesale prices or the actual acquisition cost of pharmaceuticals. Legal and equitable principles preclude this action for damages and injunctive relief.

**Thirtieth Affirmative Defense**

The claims alleged herein, based on the facts alleged, are barred in whole or in part by Plaintiff's own negligence or gross negligence and the doctrines of comparative and/or contributory negligence. Among other things, the claims disregard Iowa's obligations under federal law.

**Thirty-First Affirmative Defense**

Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because Bayer did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

**Thirty-Second Affirmative Defense**

Plaintiff has failed to plead with particularity allegations of fraud by Bayer contained in the Complaint.

**Thirty-Third Affirmative Defense**

Plaintiff's claims for fraud and fraudulent concealment are barred because the Plaintiff cannot predicate a claim for fraud on reliance by a third party.

**Thirty-Fourth Affirmative Defense**

Plaintiff's claims against Bayer are barred because Plaintiff lacks standing or capacity to bring the some or all of the claims asserted against Bayer under Iowa law.

**Thirty-Fifth Affirmative Defense**

Plaintiff's claims against Bayer are barred in whole or in part by the doctrine of voluntary payment.

**Thirty-Sixth Affirmative Defense**

Plaintiff's claims against Bayer for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Thirty-Seventh Affirmative Defense**

Plaintiff's claims against Bayer for unjust enrichment are barred because the Complaint does not allege that Defendants received any payment or property from the Plaintiff.

**Thirty-Eighth Affirmative Defense**

Plaintiff's claims against Bayer for injunctive relief against Bayer are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Thirty-Ninth Affirmative Defense**

Plaintiff's claims against Bayer are misjoined with Plaintiff's claims against other Defendants and must be severed.

**Fortieth Affirmative Defense**

Any damages recovered by the Plaintiff must be limited by any applicable statutory ceiling on recoverable damages.

**Forty-First Affirmative Defense**

To the extent punitive damages are sought, Plaintiff's punitive damages claims against Bayer (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Bayer; (3) cannot be sustained because the laws regarding the standards for determining liability for, and the amount of, punitive damages fail to give Bayer prior notice of the conduct for which punitive damages may be imposed and the severity of the

penalty that may be imposed and are void for vagueness in violation of Bayer's due process rights guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and be improper under the Iowa Constitution and Iowa common law.

**Forty-Second Affirmative Defense**

Plaintiff fails to allege facts or a cause of action against Bayer sufficient to support a claim for prejudgment interest or any other relief.

**Forty-Third Affirmative Defense**

Plaintiff has not suffered, and will not suffer, any injuries to a legally protected or cognizable interest by reason of the conduct of Bayer as alleged in the Complaint.

**Forty-Fourth Affirmative Defense**

Plaintiff's claims against Bayer are barred because Bayer has complied with all applicable regulations of the federal and state governments.

**Forty-Fifth Affirmative Defense**

Plaintiff's claims against Bayer are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superseding conduct of third parties.

**Forty-Sixth Affirmative Defense**

Plaintiff's claims against Bayer are barred, in whole or in part, because Bayer did not make any false statements to the Plaintiff. As to any statement asserted against Bayer that Plaintiff alleges to be false or misleading, Bayer had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Forty-Seventh Affirmative Defense**

Plaintiff fails to allege facts or a cause of action sufficient to support a claim against Bayer for compensatory damages, attorneys' fees, enhanced damages, treble damages and/or legal fees or costs.

**Forty-Eighth Affirmative Defense**

Bayer adopts by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

**Forty-Ninth Affirmative Defense**

Bayer hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its Answer to assert such defense.

Dated: September 18, 2008

Respectfully submitted,

/s/ Richard D. Raskin

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF BAYER CORPORATION AND BAYER HEALTHCARE PHARMACEUTICALS INC. TO THE STATE OF IOWA'S COMPLAINT was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

September 18, 2008

/s/ Richard D. Raskin  
Richard D. Raskin